APPENDIX C – 510(K) SUMMARY

MAY - 2 2001 K002186

VASCULAR ASSIST™

Submitter's Name: Ms Audrey A. Witko,
Vice President - Administration, Compliance & Clinical Affairs
Huntleigh Healthcare Inc,
40 Christopher Way
Eatontown, NJ 07724-3327
USA

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Name of Device: VASCULAR ASSIST

Manufactured by: Huntleigh Diagnostics Ltd.
35, Portmanmoor Road,
Cardiff
South Glamorgan CF24 5HN
Wales, U.K.

Contact Person at Manufacturing Facility:
B.J.Colleypriest
Telephone N°: 011-442-920-485885
Fax N°: 011-442-920-490170
e-mail: bryn.colleypriest@huntleigh-diagnostics.co.uk

Date of summary: 14 July 2000

Classification Name Cardiovascular Devices

Predicate Devices

The VASCULAR ASSIST is substantially equivalent to a combination of the following devices:-

1	Huntleigh Diagnostics Rheo Dopplex II (RD2)	K964699 & K984307.
2	IMEXLAB 9000	K973556
3	Spectradop	K925078

Device Description

The VASCULAR ASSIST is a modular, portable handheld device that provides the trained professional with maximum flexibility to carry out vascular laboratory type assessments within the hospital, doctor's surgery or the community.

Power to energize the system is supplied by a stand-alone rechargeable battery pack. Alternatively, the Assist can be powered from an AC-power supply via a power adapter.

Indications for use

Medical applications for which the device is specifically capable of measuring include:-

- Single/Dual arterial photoplethysmography (APPG)
- Single/Dual venous photoplethysmography (VPPG)
- Pulse volume recording (PVR)
- Venous reflux testing
- Semi-automatic Blood Pressure measurement

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 2 2001

Huntleigh Healthcare, Inc.
c/o Ms. Audrey A. Witko
Vice President, Administration, Compliance & Clinical Affairs
40 Christopher Way
Eatontown, NJ 07724-3327

Re: K002186
Trade Name: Vascular Assist 510(k) Application
Regulatory Class: II (two)
Product Code: DPW/JOM/JAF
Dated: January 24, 2001
Received: February 01, 2001

Dear Ms. Witko:

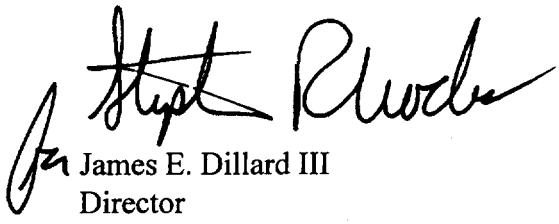
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

APPENDIX E – INDICATIONS FOR USE SUMMARY

510(k) Number (if known): K002186

Device Name: **VASCULAR ASSIST**

Indications for Use

The device is used for the assessment of blood flow in veins and arteries to assist in the identification of vascular disease.

The device can be used in the hospital, doctors office or the community by clinically trained professionals.

- The device is for non-invasive peripheral vessel use
- The device is not to be used on or near non-intact skin
- The device is not to be used on the eye and is not intended for fetal use.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices

510(k) Number K002186

Prescription Use ✖ OR Over the counter use _____

(Per 21 CFR 801.109)